

### **Remarks**

In the present application, claims 1-23, 27-35 and 43-44 are pending. Claims 1-23, 27-35 and 43-44 are rejected. Claims 24-26 and 36-42 have been previously canceled.

### **Amendment to the Claims**

Claims 1, 11, 17, 22, 27 and 29 are amended. Support for these clarifying amendments may be found throughout the specification; for example, page 13, lines 21-26 (“the ratio of the pulsatile perfusion soon after, but not immediately after, the leg has been raised”).

Claims 30-35 and 43-44 are canceled without prejudice or disclaimer.

Claims 45-72 are newly added. Support for these claims may be found throughout the specification; page 16, lines 4-8 (“the foot may be illuminated using IR light and also red light”); page 11, line 28 – page 12, line 4 (“non-pulsating signals” and “pulsating signals”).

No new matter is added.

### **Claim Rejections – 35 U.S.C. § 101**

The Examiner has rejected claims 22 under 35 U.S.C. § 101 as being directed to non-statutory subject matter. The Applicants assert that this claim, as presently presented, overcomes the rejection and respectfully request the Examiner withdraw the rejection to claim 22.

### **Claim Rejection - 35 U.S.C. § 103(a)**

The Examiner has rejected claims 1-23 and 27-35 as being unpatentable under 35 U.S.C. § 103(a) over Rathgeber et al. (“Influence of different types of recovery positions on perfusion indices of the forearm”), herein Rathgeber, in view of Dekker (U.S. Patent Publication No. 2003/0163033), herein Dekker; and claim 43 as being unpatentable under 35 U.S.C. § 103(a) over Rathgeber Dekker and further in view of Vegfors et al. (“The influence of changes in blood flow on the accuracy of pulse oximetry in humans”), herein Vegfors. The Applicant includes the following comments to clearly distinguish the claimed invention over the art cited by the Examiner, and respectfully requests a favorable reconsideration of claims 1-23 and 27-29.

These rejections are respectfully disagreed with, and are traversed below.

The Examiner is respectfully reminded that, in accordance with the MPEP, the Examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Examiner must ascertain the differences between the claimed invention and the prior art. However, the gap between the prior art and the claimed invention may not be so great as to render the claim nonobvious (see MPEP § 2141-2142).

Regarding claim 1, which recites:

“A system for producing a quantitative indicator that measures a response of a subject’s blood circulation system to postural change, comprising:

pre-processing circuitry configured to detect a signal dependent upon an arterial blood volume in the limb of the subject when the subject is **in a first posture** and configured to detect the **signal dependent upon the arterial blood volume in the limb of the subject responsive to a change in the subject’s posture from the first posture to a second posture, different to the first posture**; and

processing circuitry configured to **calculate a quantitative indicator that measures a response of the subject’s blood circulation system to postural change and is dependent upon a ratio of the detected signal for the first posture prior to the postural change to the detected signal for the second posture after the postural change and during a response of the subject’s blood circulation system to the postural change**” (emphasis added).

Rathgeber is a document published in the specialist journal ‘Resuscitation’. It is concerned with the evaluation of the effect on a person of different recovery positions when held for extended periods (see pg 17, left column, last paragraph, “In summary, for positioning over extended periods”). It is particularly concerned with straining of the brachial plexus. Many different indices are plotted to assess impairment of the arterial blood flow, venous drainage and nerve function (see Fig 6-9). The parameters plotted are: photoplethysmographic pulsatility index (PPI), photoplethysmographic volume index (PVI), invasive peripheral venous pressure (PVP) and non-invasive blood pressure amplitude (PBA). In addition, non-qualitative subjective discomfort was assessed.

The protocol used by Rathgeber uses as the control group healthy volunteers and the plotting of the same parameters and uses as the variable different recovery positions. Each

volunteer is supine, then moved to one recovery position for 15 minutes (only the last 5 minutes of the 15 minutes period are used for measurement), then made supine, then moved to another recovery position for 15 minutes (only the last 5 minutes of the 15 minutes period are used for measurement).

The ratio calculated by Rathgeber is not the same as the ratio determined by the invention of claim 11 (“a ratio of the signal for the first posture to the signal for the second posture”). The PPI is a new index for the assessment of recovery positions. As seen above, Rathgeber is concerned with **effects of recovery positioning** over extended periods. In contrast, the present invention is concerned with the circulatory response to a posture **change**.

As Rathgeber is concerned with the effects over an extended period, it proposes the determination of particular indexes. Ten (10) minutes after a healthy subject has been put into a recovery position measurements are started and are continued for 5 minutes. The measurements are averaged over the 5 minute period. The average is then normalized.

The PPI is dependent on a ratio of a long term (5 minute) **average** of a detected signal in a first posture to a long term (5 minute) **average** of a detected signal in a second posture. The long term averaging performed in Rathgeber make the PPI different from the quantitative indicator claimed. Thus, Rathgeber does not disclose “a quantitative indicator that measures a response of the subject’s blood circulation system to postural change and is dependent upon a ratio of the detected signal for the first posture prior to the postural change to the detected signal for the second posture after the postural change and during a response of the subject’s blood circulation system to the postural change”.

The long-term averaging is a necessary feature of Rathgeber’s teaching as Rathgeber is interested in comparing the effects of different recovery positions when held for extended periods. There would therefore be no reason whatsoever to determine “a ratio of the detected signal for the first posture prior to the postural change to the detected signal for the second posture after the postural change and during a response of the subject’s blood circulation system to the postural change” instead of a ratio of a long term **average** of detected signals in a first posture to a long term **average** of detected signals in a second posture.

In short, the signal and qualitative indicator that is required by the invention of claim 1 (which captures the circulatory response to a postural change) is of no interest whatsoever to Rathgeber. Rathgeber instead delays taking measurements until 10 minutes after the postural

change and then averages over 5 minutes. Thus the PPI index taught by Rathgeber although superficially similar to the quantitative indicator claimed is in fact very different and that difference is defined in claim 1.

Additionally, Rathgeber does not disclose or suggest processing circuitry configured to calculate a quantitative indicator that measures a response of the subject's blood circulation system to postural change and is dependent upon a ratio of the detected signal for the first posture prior to the postural change to the detected signal for the second posture after the postural change and during a response of the subject's blood circulation system to the postural change.

Rathgeber seems to teach that the PPI index is determined by the clinician from a plot of the pulse oximeter signal (see Fig 5). Certainly there is no disclosure of how the AC signal might be separated from the DC signal other than by a clinician observing the plot of Fig 5.

Rathgeber teaches that the PPI index is calculated for 20 healthy volunteers. Rathgeber's conclusion is that the AHA recovery position is superior and suggests that any future recovery position should be subjected to a similar evaluation for comparison against the results achieved by Rathgeber. This would appear to indicate that when (if) a new recovery position is developed it should be evaluated in the same way and compared to Rathgeber's data. This would seem to be a teaching against modifying the procedure and approach of Rathgeber. Certainly there is no suggestion that the procedure and approach of Rathgeber should be changed.

Even if a new recovery position were to be proposed, there would be no motivation to change the procedure and approach of Rathgeber as only 20 measurements would be required. The 'cost' of such measurements would not be enough to motivate the clinician to automate the approach and procedure.

In addition Rathgeber teaches the monitoring of 4 different quantitative indexes and also a non-qualitative comfort index. It is not clear how the assessment of all of these indexes would be automated.

There is therefore no reason for the teaching of Rathgeber to be automated if the teaching of Rathgeber is used in its original technical field namely occasional comparative assessments of a new recovery position. There is also no reason whatsoever why someone

would seek to use the teachings of Rathgeber in any other technical field than occasional comparative assessments of a new recovery position.

The PPI index, for example, is an index created specifically by Rathgeber for the assessment of recovery positions. It has no known other use. There is therefore no 'secondary market' for the PPI index that would create any motivation for automation.

Even if for some unknown reason a person of ordinary skill in the art wished to automate the approach and procedure of Rathgeber there is no clear teaching of how this would be achieved.

Thus, Rathgeber does not disclose or suggest to "calculate a quantitative indicator that measures a response of the subject's blood circulation system to postural change and is dependent upon a ratio of the detected signal for the first posture prior to the postural change to the detected signal for the second posture after the postural change and during a response of the subject's blood circulation system to the postural change" as in claim 1.

Dekker teaches an apparatus and method for monitoring a secondary physiological process through variations caused by the secondary process in an optical signal used to calculate values related to blood oxygen levels and by measuring fluctuations in a DC component of blood oxygenation.

The Examiner alleges that Dekker discloses a processor that calculates a quantitative indicator that is dependent upon a ratio of a signal for a first posture and a second posture. Rather, Dekker is completely silent concerning **postural change**. Dekker is concerned with measuring slow variations in the DC component of blood oxygenation to determine respiration/heart rate. Dekker appears to disclose the calculation of a ratio of a signal for a first wavelength to a signal for a second wavelength (see Equation 11). However, the calculation of a ratio of a signal for a first wavelength to a signal for a second wavelength is standard practice in pulse oximetry (see Equations 6 and 8).

As neither Rathgeber nor Dekker disclose to "calculate a quantitative indicator that measures a response of the subject's blood circulation system to postural change and is dependent upon a ratio of the detected signal for the first posture prior to the postural change

to the detected signal for the second posture after the postural change and during a response of the subject's blood circulation system to the postural change", no combination of the teachings of Rathgeber and Dekker can result in the invention claimed in claim 1.

Dekker relates to monitoring respiration/heart rate of an unhealthy patient using pulse oximetry (differential wavelength measurements). Rathgeber relates to monitoring the effect of a recovery position on a healthy subject. Consequently the prior art documents are from unrelated technical fields and the person of ordinary skill in the art would not seek to combine their teaching.

The prior art documents teach away from the claimed combination of features. Neither Rathgeber nor Dekker discloses calculating the quantitative indicator as claimed. The PPI presented in Rathgeber is not the same as the quantitative indicator claimed because the PPI is a long term averaged signal determined a long time after the posture change, whereas the quantitative indicator measures a **response to postural change**. Dekker is concerned with slowly varying changes in the DC component of a pulse oximetry signal. It suggests that the signals may be averaged over a given period of time (see paragraph [0052]). There is no disclosure or suggestion that would lead a person of ordinary skill to modify the PPI.

Furthermore, even if Dekker were to motivate a modification of PPI (which the Applicants do not assert) then the skilled person would not seek to combine the teachings of Rathgeber and Dekker as such a modification would change the principle of operation of Rathgeber.

Finally, there is no obvious benefit/advantage to making the combination the examiner has suggested. Rathgeber relates to an approach and procedure that is not unduly intensive for a clinician and which will be performed infrequently. It would not be obvious to try and use a processor in Rathgeber because the multiple different parameters used would make the cost of trying prohibitive compared to the advantage gained.

In the Response to Arguments section, the Examiner indicates that the claims, as previously presented, were interpreted to not limit "the calculation of a "quantitative indicator" in any way, other than it be a ratio of a signal in a first posture to a signal in a second posture". The Applicants assert, that the claims, as presently presented, overcome this

interpretation, for example, by defining a “signal dependent upon the arterial blood volume in the limb of the subject responsive to a change in the subject’s posture from the first posture to a second posture, different to the first posture” as in claim 1.

As neither Rathgeber nor Dekker discloses or suggests “to detect the signal dependent upon the arterial blood volume in the limb of the subject responsive to a change in the subject’s posture from the first posture to a second posture, different to the first posture” and “to calculate a quantitative indicator that measures a response of the subject’s blood circulation system to postural change and is dependent upon a ratio of the detected signal for the first posture prior to the postural change to the detected signal for the second posture after the postural change and during a response of the subject’s blood circulation system to the postural change” as in claim 1, the combination of Rathgeber and Dekker (which the Applicants do not assert there is a motivation to so combine or that such a combination is feasible), herein Rathgeber-Dekker, also does not disclose or suggest these elements of claim 1. As Rathgeber-Dekker does not disclose or suggest all elements of claim 1, claim 1 is not made obvious by Rathgeber-Dekker. For at least this reason, claim 1 is in condition for allowance.

As claims 11, 17 and 27 recite similar language to that discussed above with reference to claim 1, claims 11, 17 and 27 are likewise in condition for allowance. Claims 2-10, 18-23 and 28-29 depend upon claims 11, 17 and 27. For at least this reason, they are likewise in condition for allowance.

In light of the discussion above, the Applicant respectfully asserts that a prima facie case for obviousness was not presented. As such, the Applicant respectfully requests that the Examiner reconsider and withdraw these rejections to claims 1-23 and 27-29.

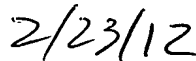
Newly added claims 45-72 either recite similar language to that discussed above with reference to claim 1, 11, 17 and 27 or depend from claims 1, 11, 17 and 27. As seen above, claims 1, 11, 17 and 27 are in condition for allowance. For at least this reason, claims 45-72 are likewise in condition for allowance.

For the foregoing reasons, the Applicant believes that each and every issue raised by the Examiner has been adequately addressed and that this application is in condition for allowance. As such, early and favorable action is respectfully solicited.

Respectfully submitted:



Ricardo Ochoa



Date

Reg. No.: 61,545

Customer No.: 29,683

HARRINGTON AND SMITH, ATTORNEYS AT LAW, LLC

4 Research Drive

Shelton, CT 06484-6212

Telephone: (203) 925-9400 x24

Facsimile: (203) 944-0245

Email: ROchoa@HSPatent.com